

Louisiana Medicaid Tolvaptan (Jynarque®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for tolvaptan (Jynarque®).

Additional Point-of-Sale edits may apply.

*Jynarque® has a **Black Box Warning** and is subjected to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to prescribing information for details.*

Approval Criteria

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of autosomal dominant polycystic kidney disease (ADPKD); **AND**
- The recipient is at risk of rapidly progressing ADPKD, which is **stated on the request**; **AND**
- The recipient is **NOT** on dialysis, which is **stated on the request**; **AND**
- Tolvaptan (Jynarque®) has been prescribed by, or in consultation with, a nephrologist; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The recipient has no contraindications to treatment with tolvaptan (Jynarque®); **AND**
 - Liver function (ALT, AST and bilirubin) will be measured before initiating treatment, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months and every 3 months thereafter; **AND**
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 3 months

Reauthorization Criteria

- The recipient has a diagnosis of autosomal dominant polycystic kidney disease (ADPKD); **AND**
- The prescriber **states on the request** that the recipient has received clinical benefit from treatment with the requested agent; **AND**
- By submitting the authorization request, the prescriber attests that the recipient has no contraindications to continued treatment with the requested agent and that ongoing monitoring will be completed as recommended in the prescribing information.

Duration of reauthorization approval: 12 months

Reference

Jynarque (tolvaptan) [package insert]. Rockville, MD: Otsuka America Pharmaceutical Co., Ltd; February 2019. <https://www.otsuka-us.com/media/static/JYNARQUE-PI.pdf>

Revision	Date
Policy created.	January 2020
Policy implemented.	May 2020